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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,516	03/06/2002	Peter Wagner	P/ 37-171	9644
2352	7590	09/07/2006	EXAMINER	
OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			CONLEY, SEAN EVERETT	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/937,516

Applicant(s)

WAGNER, PETER

Examiner

Sean E. Conley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31 and 55-57 is/are rejected.
- 7) ☒ Claim(s) 30 and 32-54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed June 15, 2006 has been received and considered for examination. Claims 26-57 are pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 26-29, 31 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanderson et al. (U.S. Patent No. 4,349,118).

Regarding claims 26, 28 and 55, Sanderson et al. discloses a sterilization container (base (10) combined with lid (12)) for holding items to be passed through a sterilization process (see col. 3, lines 1-16); the container having a valve arrangement (58) permitting a medium exchange between an inside and an outside of the sterilization container during the sterilization process (see col. 3, lines 52-59), the valve arrangement (58) comprising: an open position of the valve arrangement to permit the exchange of the medium and a closed position of the valve arrangement to prevent the exchange of the medium; a valve body (60) responsive to a pressure flow to urge the valve arrangement to the closed position; a stop (latch (86) contacting latch lever (78))

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in the valve arrangement, the stop (86) having a stop position to prevent the valve arrangement from moving to the closed position; and a temperature sensor (fuse metal (84) in housing (82)) coupled to the stop and operable to urge the stop away from the stop position based on a set temperature reached before the ventilation phase, wherein the temperature sensor is protected from premature cooling by the fact that the valve body (60) remains closed during cooling by latch (86) and the valve is only opened by depressing manual level (74) and resetting the stop (latch (84)) so that the valve is in an open position (see figures 1, 5 and 6; col. 3, line 60 to col. 4, line 57; col. 5, lines 3-38; col. 6, lines 23-45).

Regarding claims 27 and 29, Sanderson et al. discloses that the temperature sensor (fuse metal (84)) exhibits hysteresis based on temperature (see col. 5, lines 11-22; col. 6, lines 23-25).

Regarding claim 31, Sanderson et al. discloses a recess (54) at a bottom portion of the sterilization container (see figure 5; col. 3, lines 52-59). The valve arrangement (58) being located in the recess and operable to permit condensate formed during the sterilization process to drain from the bottom portion through the valve arrangement.

Regarding claims 56 and 57, Sanderson et al. discloses a method of operating a valve in a sterilization container for holding items to be passed through a sterilization process in a sterilizer, comprising: setting a blocking pin (latching lever (78)) in a position to cooperate with a stop (86) to prevent closure of the valve; exposing the sterilization container and the valve to a sterilization phase while maintaining the blocking pin position; increasing a temperature applied to the sterilization container and

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valve to heat the valve beyond a set temperature; moving the blocking pin to a position to prevent cooperation with the stop in response to obtaining a temperature for the valve above the set temperature; closing the valve in response to a pressure differential, whereby the sterilization container maintains a vacuum. The process further includes the step of removing residual steam while the valve is opened so that the container is maintained in a dry state (see col. 4, line 58 to col. 5, line 67).

***Allowable Subject Matter***

3. Claims 30 and 32-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 30 and 44-51, the prior art, alone or in combination, fail to teach or fairly suggest a sterilization container with a temperature sensor that further comprises a snap-disk stack having a plurality of snap disks each having a shape that varies responsive to temperature changes; and at least two of the snap-disks in the snap-disk stack having different respective temperature behaviors.

Regarding claims 32-43 and 52-54, the prior art alone or in combination, fails to teach or fairly suggest a sterilization container further comprising a central wall section in the bottom and having a conical shape that is tapered inward in an upward direction; perforation openings in the central wall section to permit condensate to drain through the perforation openings when the valve arrangement is in the open position; an annular valve seat surrounding the perforation openings; and the valve body having a valve

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plate and a valve ring on the valve plate, the valve ring cooperating with the annular valve seat to seal the sterilization chamber.

The closest prior art to the applicant's claimed invention is Wagner (U.S. Patent No. 5,352,416). Wagner discloses a sterilization container for holding sterilized items to be passed through a sterilization process in a sterilizer that includes a vacuum drying phase and a ventilation phase, the container is capable of remaining hermetically sealed and maintaining a vacuum established during the sterilization process; the container having a valve arrangement permitting an exchange of a medium between the sterilizer and the sterilization container during the sterilization process, the valve arrangement comprising, an open position of the valve arrangement to permit the exchange of the medium and a closed position of the valve arrangement operable to prevent the exchange of the medium; and a temperature sensor in the valve arrangement operable to prevent the valve arrangement from moving to the closed position until a set temperature cycle of the sterilizer is complete (see figures 1 and 10, column 1, lines 35-63, and column 4, lines 9-63).

However, Wagner fails to teach the specific elements recited in dependent claims 30 and 32. Therefore, claims 30 and 32-54 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

4. Applicant's arguments filed June 15, 2006 have been fully considered but they are not persuasive.

Regarding claim 26, the Applicant first argues that Sanderson et al. fails to disclose a sterilization container including "a valve body responsive to a pressure flow to urge the valve arrangement to the closed position" as required by claim 26 of the present application. The examiner respectfully disagrees. Sanderson et al. discloses a device wherein heated steam melts a fuse and thus a spring (75) urges the valve body into a closed position. The heated steam presents an increased pressure flow in addition to an increased temperature which has an indirect impact on the closing of the valve body. The valve body responds to heated steam (which includes a pressure flow) and melts the fuse (84) to urge the valve closed.

Also, regarding claim 26, the Applicant argues that Sanderson et al. fails to disclose a sterilization container including a temperature sensor coupled to the stop and operable to urge the stop away from the stop position based on a set temperature reached before or during the ventilation phase. The Applicant provides a basis for this argument by stating that the fuse (84) in Sanderson et al. melts during the high temperature sterilization exposure phase substantially before the beginning of the ventilation phase as apposed to "just" before the ventilation phase as recited in claim 26. The examiner respectfully disagrees. The limitation of when the temperature sensor urges the stop away from the stop position is directed to an intended use of the

invention. The fuse (84) in Sanderson et al. is capable of melting just before the beginning of the ventilation phase as recited by claim 26.

Regarding claim 27, The Applicant argues that Sanderson et al. does not describe hysteresis and instead discusses a time delay in the reaction of the temperature sensor which has one closing temperature. The Applicant further states that a simple time delay is not an example of hysteresis. The examiner respectfully disagrees. Hysteresis is defined as the lagging of an effect behind its cause (see The American Heritage Dictionary definition of hysteresis). A time delay between the heating of the fuse (temperature sensor) and the melting of the sensor is a perfect example of hysteresis according to the definition because the heat from the steam is the cause and the effect is the melting of the fuse with the time delay providing evident of the lagging between the heating and the melting of the fuse.

Regarding claims 28 and 55, the Applicant argues that Sanderson et al. fails to disclose preventing premature cooling of the temperature sensor. The examiner respectfully disagrees. The design of the valve in Sanderson et al. provides a valve body that remains physically closed during a cooling process (due to forces caused by spring (75)) and therefore the valve is protected and isolated from the effects of cooling. A cooling process does not cause the rubber-like valve body of Sanderson et al. to move into an open position.

Regarding claim 56, the Applicant argues that Sanderson et al. fails to disclose a method for operating a valve in a sterilization container including "closing the valve in response to a pressure differential" as required by claim 56. The examiner respectfully



disagrees. Sanderson et al. discloses that the valve body is closed in response to heated steam which melts the fuse, thus creating a pressure differential on the valve body which enables spring (75) to urge the valve body to a closed position.

Finally, the Applicant states that the claims 26, 28, and 55 have been amended to include four phases of a sterilization process, namely, a conditioning phase, a high temperature phase sterilization exposure phase, a vacuum drying phase, and a ventilation/aeration phase. The Applicant argues that the valve body of the present invention remains open until the ventilation/aeration phase, or at least just prior to the ventilation/aeration phase, whereas Sanderson et al. discloses that the valve body (60) is switched into the closed position at the end of the high temperature sterilization exposure phase. The examiner respectfully disagrees. The limitation of when the temperature sensor urges the stop away from the stop position is directed to an intended use of the invention. The fuse (84) in Sanderson et al. is capable of melting just before the beginning of the ventilation phase as recited by claim 26. The various phases only represent an intended use of the device and can occur in any order or at various times during a process.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

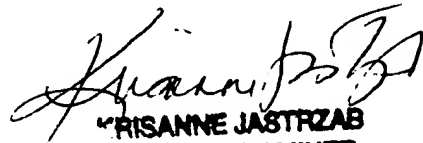
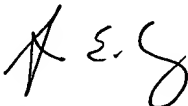
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEC

August 28, 2006



KRISANNE JASTRZAB  
PRIMARY EXAMINER